K132466
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# Traditional 510(k) Summary

The following 510(k) summary has been prepared pursuant to requirements specified in 21CFR 807.92.

807.92(a)(1)

## Submitter Information

Esaote S.p.A.
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DEC 0 4 2013

Contact Person: Allison Scott
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Date: August 6, 2013

807.92(a)(2)

## Devices

Common Name: Ultrasound Imaging System

Trade Name: 6400 Ultrasound System
7400 Ultrasound System

Classification Name(s): Ultrasound Pulse Doppler Imaging System 892.1550
Ultrasound Pulse Echo Imaging System 892.1560
Transducer, Ultrasonic, Diagnostic 892.1570

Classification Number: 90IYN, 90IYO, 90ITX

807.92(a)(3)

## Predicate Device(s)

| Device | Owner | 510(k) |
|---|---|---|
| 6400<br>7400 | Esaote | K111302 |
| AU6 (Technos) | Esaote (Biosound Esaote) | K990360, K000681, K014168, K023255 |
| 6200 | Esaote | K100931 |

807.92(a)(4)

## Device Description

Model 6400 is a mainframe system equipped with wheels allowing to move the system. Model 7400 is a portable system equipped with a handle. The system size and weight allow it to be carried using its handle. The primary modes of operation are for both models: B-Mode, M-Mode, Tissue Enhancement Imaging (TEI), XView, Multi View (MView), Trapezoidal View (TPView), Doppler, Color Flow Mapping (CFM), Amplitude Doppler (AD) and Tissue Velocity Mapping (TVM). Both 6400 and 7400 are equipped with a LCD color display where acquired images and advanced image features are shown. Both 6400 and 7400 can drive Phased, Convex, Linear array and Doppler probes.. 6400 control panel is equipped with a pull-out Qwerty alphanumeric keyboard that allows data entry. On 7400 model the touchscreen has an emulation of the Qwerty alphanumeric keyboard that allows data entry. Both 6400 and 7400 models are equipped with wireless capability. Model 7400 has been designed to be powered by battery.

Both 6400 and 7400 have been cleared via k111302.

6400 and 7400 Upgrades, defined herein, combine the cleared features of both 6400 and 7400 systems with new capabilities, listed below:

1. Managing of Intraoperative (Abdominal) application on both 6400 and 7400 upgrades.
2. Management of Pulsed Wave (PW) Doppler probe on both 6400 and 7400 upgrades.

The 6400 and 7400 Upgrades are manufactured under an ISO 9001:2000 and ISO 13485 certified quality system.

807.92(a)(5)

## Intended Use

Esaote's Model 6400 is a mainframe ultrasound system used to perform diagnostic general ultrasound studies including Cardiac, Transesophageal Cardiac, Peripheral Vascular, Neonatal Cephalic, Adult Cephalic, Small organs, Musculoskeletal (Conventional and Superficial), Abdominal, Fetal, Transvaginal, Transrectal, Pediatric, Intraoperative abdomninal and Other: Urologic. The 6400 system provides imaging for guidance of biopsy and imaging to assist in the placement of needles in vascular or other anatomical structures as well as peripheral nerve blocks in Musculoskeletal applications.

Esaote's Model 7400 is a compact ultrasound system used to perform diagnostic general ultrasound studies including Cardiac, Transesophageal Cardiac, Peripheral Vascular, Neonatal Cephalic, Adult Cephalic, Small organs, Musculoskeletal (Conventional and Superficial), Abdominal, Fetal, Transvaginal, Transrectal, Pediatric, Intraoperative abdomninal and Other: Urologic. The 7400 system provides imaging for guidance of biopsy and imaging to assist in the placement of needles in vascular or other anatomical structures as well as peripheral nerve blocks in Musculoskeletal applications.

807.92(a)(6)

## Technological Characteristics

The 6400 and 7400 Upgrades employ the same fundamental technological characteristics as their predicate devices. The 6400 Upgrade model is substantially equivalent to Esaote AU6 (Technos) model cleared via K990360, K000681, K014168, K023255, to Esaote 6200 model cleared by FDA via K100931 and to Esaote 6400 model cleared by FDA via K111302. The 7400 Upgrade model is substantially equivalent to Esaote AU6 (Technos) model cleared via K990360, K000681, K014168, K023255, to Esaote 6200 model cleared by FDA via K100931 and to Esaote 7400 model cleared by FDA via K111302.

- Clinical uses for which Esaote 6400 and 7400 models, cleared by FDA via K111302, are designed are not changed by 6400 and 7400 Upgrades, to be cleared via this submission.
- Clinical uses for which Esaote 6400 and 7400 Upgrades are designed are equivalent to those of Esaote 6200 model, cleared via K100931, and of Esaote AU6 (Technos) model, cleared via K990360, K000681, K014168, K023255.
- 6400 Upgrade and 7400 upgrade for managing Intraoperative (abdominal) application are equivalent to those of Esaote 6200 model, cleared via K100931.
- 6400 and 7400 Upgrades for managing Pulsed Wave (PW) Doppler probe are equivalent to those of Esaote AU6 (Technos) model, cleared via K990360, K000681, K014168, K023255.
- Esaote 6400 Upgrade, 7400 Upgrade, 6400, 7400, 6200 and AU6 (Technos) are designed to meet the IEC60601-1.
- Esaote 6400 Upgrade, 7400 Upgrade, 6400, 7400 and 6200 are designed to meet the IEC60601-1 and IEC60601-2-37 safety requirements.
- Esaote 6400 Upgrade, 7400 Upgrade, 6400, 7400, 6200 and AU6 (Technos) ultrasound models provide an Acoustic Output Display feature per AIUM / NEMA standards, with equivalent Ispta and MI maximal values.

807.92(b)(1)

## Summary of Non-Clinical Tests

The devices have been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic, and mechanical safety, and have been found to conform to the following medical device safety standards.

- IEC 60601-1
- IEC 60601-1-2
- IEC 6060 1-2-37
- NEMA UD-3 - Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- NEMA UD-2 - Acoustic Output Measurement Standard for Diagnostic Ultrasound

807.92(b)(2)

## Summary of Clinical Tests

No clinical tests were performed.

807.92(b)(3)

## Conclusion

**The 6400 and 7400 Upgrades are substantially equivalent to the legally marketed devices and conform to applicable medical device safety and performance standards.**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 4, 2013

Esaote S.p.A.
% Allison Scott, RAC
Senior Consultant
9001 Wesleyan Road, Suite 200
INDIANAPOLIS IN 46268

Re: K132466
Trade/Device Name: MyLabSeven 6400, MyLabAlpha 7400
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: November 11, 2013
Received: November 13, 2013

Dear Ms. Scott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

This determination of substantial equivalence applies to the following transducers intended for use with the MyLabSeven 6400 and MyLabalpha 7400, as described in your premarket notification:

Transducer Model Number

| | | |
|---|---|---|
| SP2430 | S2MCW | TRT33[1] |
| LA523[1] | S5MCW | ST2612 |
| AL2442 | SHFCW | IOT342 |
| AL2443 | S2MPW | IOT332[1] |
| AC2541 | SE3123 | |

[1] For 6400 systems only

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

# 6400 and 7400 Systems

## Indications for Use

510(k) Number (if known): K132466

Device Name: 6400 and 7400 Ultrasound Systems

Esaote's Model 6400 is a mainframe ultrasound system used to perform diagnostic general ultrasound studies including Cardiac, Transesophageal Cardiac, Peripheral Vascular, Neonatal Cephalic, Adult Cephalic, Small organs, Musculoskeletal (Conventional and Superficial), Abdominal, Fetal, Transvaginal, Transrectal, Pediatric, Intraoperative abdominal and Other: Urologic. The 6400 system provides imaging for guidance of biopsy and imaging to assist in the placement of needles in vascular or other anatomical structures as well as peripheral nerve blocks in Musculoskeletal applications.

Esaote's Model 7400 is a compact ultrasound system used to perform diagnostic general ultrasound studies including Cardiac, Transesophageal Cardiac, Peripheral Vascular, Neonatal Cephalic, Adult Cephalic, Small organs, Musculoskeletal (Conventional and Superficial), Abdominal, Fetal, Transvaginal, Transrectal, Pediatric, Intraoperative abdominal and Other: Urologic. The 7400 system provides imaging for guidance of biopsy and imaging to assist in the placement of needles in vascular or other anatomical structures as well as peripheral nerve blocks in Musculoskeletal applications.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health
510(k) _____K132466_____

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